



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY - 2 2002

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Comments on **1,2-Benzisothiazolin-3-one, 2-butyl [Vanquish 100]**

1,2-Benzisothiazolin-3-one, 2-butyl [Vanquish 100]

EPA Reg. No.: 072674-E

DP Barcodes: D282463

PC Code: 098951

Case: 062095

From: S. L. Malish, Ph.D., Toxicologist, *S. L. Malish 4/25/02*
Risk Assessment and Science Support Branch (RASSB), Antimicrobials Division
(AD)[7510C]

To: Marshall Swindell, PM 33
PM Team Reviewer, Martha Terry
Regulatory Management Branch
Antimicrobials Division [7510C]

Thru: Siroos Mostaghimi, Acting Team Leader,
Team One, RASSB/AD [7510C] *siroos - Mostaghimi*

and

Norman Cook, Chief, RASSB/AD [7510C] *2/2/02 CWK 05/02/02*

Applicant: Avecia Inc. Wilmington, DE

Uses: This substance is a **non-food use/non-food contact** antimicrobial for the control of fungi and bacteria in protection of natural rubber and plastic products.

BACKGROUND: A letter containing additional information came from Elizabeth A. Brown, ChemReg, Int. March 1, 2002, and was addressed to Marshall Swindell, PM 33.

ACTION REQUESTED: Review additional information and [1] determine if a Guideline/Acceptable classification can be given for a previously submitted UDS study, and [2] can a waiver be given for the proposed 90 day inhalation study?

CONCLUSIONS:

Unscheduled DNA Synthesis Study [OPPTS 870.5550 (§84-2)]

The Agency notes that mutagenicity studies performed for the Agency need to have the MTD incorporated into the main study. In this case 800 mg/kg, used in the study was not the MTD. A higher dose could have been chosen between 800 and 1250 mg/kg/day and pathological evidence provided as evidence of liver pathology.

This study does not have to be repeated and will be used for supplementary information. All study requirements in the mutagenicity battery have been fulfilled.

90 Day Inhalation Study [OPPTS 870.3465 (§82-3)]

While it is true that the test substance has a very low vapor pressure of (1.48×10^{-7}) , this value is usually obtained at a specific temperature and pressure. The elevated temperature used in molding the plastic would lead to a greater volatilization of the test material and some inhalation toxicology data must be obtained.

A waiver, therefore, cannot be granted for the 90 Day Inhalation study.